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09/380,932 01/18/00 FIRTH

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EXAMINER

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ART UNIT	PAPER NUMBER
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1635

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DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No. <b>09/380,932</b>	Applicant(s) <b>FIRTH</b>
Examiner <b>Mark L. Shibuya</b>	Group Art Unit <b>1635</b>

 Responsive to communication(s) filed on Feb 28, 2000 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims** Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

 Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 1-18 and 21-27 is/are rejected. Claim(s) 19 and 20 is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: EPO 98/42867, filed 21 March 1998

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Nucleotide and/or Amino Acid Sequence Disclosure***

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): The text of the specification discloses nucleotide or amino acid sequences but the this application does not contain, as a separate part of the disclosure on paper copy, a “Sequence Listing” as required by 37 C.F.R. 1.821(c). Also, a copy of the “Sequence Listing” in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

Applicant must provide:

- a. An initial computer readable form (CRF) copy of the “Sequence Listing”.
  - b. An initial paper copy of the “Sequence Listing”, as well as an amendment directing its entry into the specification.
  - c. A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
2. Applicant discloses nucleotide sequences in the specification that must be identified by a SEQ ID number, pursuant to 37 CFR 1.821(d), which states: “Where the description or claims of a patent application discuss a sequence listing that is set forth in the ‘Sequence Listing’ in

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accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.” Examples of such nucleotide sequences that occur in the instant specification include the three sequence on page 54 and nucleotide sequences on pages 55, 57, 70, 73, 82.

3. Applicant is required to comply with the corrections for the sequence listing as per above as part of a complete response to this official action.

*Priority*

4. Acknowledgment is made that the instant application is the national stage application under 35 U.S.C. 371, of PCT/GB98/00840, international application filed 3/20/98.

5. Acknowledgment is made of applicant's claim for foreign priority based on an application, **EPO 98/42867, filed 21 March 1998**, filed in the instant application 09/380,932, on 1/18/2000. It is noted, however, that applicant has not filed a certified copy of said EPO 98/42867 application, dated 21 March 1998, as required by 35 U.S.C. 119(b).

6. Receipt is acknowledged of priority document **EPO 97301917.7, filed March 21, 1997**, filed in the instant application, 09/380,932, “filing date” 1/18/2000, purporting to comply with the requirements of 35 U.S.C. 119(a)-(d) and said priority document has been placed of record in the file. Attention is directed to the fact that the declaration of the instant patent application 09/380,932, filed 1/18/2000, claims benefit of foreign application **EPO 98/42867, filed 21 March 1998**, (a different application, *see* immediately preceding paragraph). However, the priority data

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disclosed in international publication WO 98/42867 A1 of international application number PCT/GB98/00840, of which the instant application is a national stage application under 35 U.S.C. 371, is to **EPO 97301917.7, filed March 21, 1997**. Apparently, the declaration as filed is defective because it claims foreign priority to the “wrong” application. *See below*, objection to the declaration.

***Oath/Declaration***

7. Receipt is acknowledged of priority document EPO 97301917.7, filed March 21, 1997, seemingly filed under 35 U.S.C. 119 (a)-(d). Apparently, applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath or declaration does not acknowledge the filing of said foreign application. It is noted that foreign priority *is* claimed for EPO 98/42867, filed 21 March 1998, however no priority document of EPO 98/42867, filed 21 March 1998, has been filed in the instant application. Therefore, if applicant actually seeks foreign priority to EPO 97301917.7, filed March 21, 1997, a new oath or declaration is required in the body of which that application should be identified by application number and filing date. *See above*, objection under Priority.

***Specification***

8. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(1). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

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***Claim Objections***

9. Claims 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 19 and 20, drawn to a method wherein at least one VNTR allele is hybridized with a mixture of VNTR alleles which **do not** manifest a trait of interest, do not include every limitation of parent claim 16, drawn to a method comprising a mixture of polymorphic alleles which **do** manifest a trait of interest.

***Claim Rejections - 35 U.S.C. § 101***

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 11 and 12 are drawn to a portion of genomic DNA consisting essentially of a representative mixture of alleles of a chosen VNTR sequence and their flanking regions and wherein the alleles is representative of a trait of interest. These claims read upon naturally occurring genomes, which are products of nature that do not clearly show the “hand of man”. Language at the beginning of this claim such as “An isolated portion of genomic DNA” would remove the instant rejection.

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12. Claims 1-10, 21, and 25-27 are rejected under 35 U.S.C. 101 because the claimed recitation of a **use**, without setting forth any steps involved in the process, results in an improper definition of a process, *i.e.*, results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 U.S.C. § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-10, 13, and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-10, 21, and 25-27 provide for the **use** of a portion of genomic DNA, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this **use** is actually practiced.

b. Claims 9, 10, 22-24, 26 and 27 recite the language “of those”, which renders the claims vague and indefinite because it is not clear whether “those” refers to “flanking sequences” or “at least one VNTR allele”, or both.

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c. Claim 13 recites the limitation "each member of the mixture" in line 2. There is indefinite antecedent basis for this limitation, *i.e.*, "member of the mixture", in the claim, although the claim does recites "members of a species of interest".

***Claim Rejections - 35 U.S.C. § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 11-15 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgante et al., WO 96/17082, (applicant's reference B1, IDS filed 11/22/99).

a. Morgante et al., WO 96/17082, at p. 12, lines 8-16, p. 18, lines 1-21, p. 49, lines 16-19, p. 51, line 16-26, p. 76, line 12-p. 77, lines 6, Table IV, p. 81, lines 5-19, p. 91, lines 15-20, p. 99, lines 10-26, disclose isolated genomic DNA of one or more members of a species of interest, including soy, wherein said genomic DNA comprises a representative mixture of alleles of a chosen VNTR sequence and their flanking alleles on both sides, wherein the mixture is representative of those which manifest a trait of interest, wherein each "allele" has an adaptor at each of its 3'-end and its 5'-end, and methods for a diagnostic assay comprising said genomic DNA.

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17. Claims 16 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al., (applicant's reference C6, IDS filed 11/22/99).

a. Nelson et al. (C6), at p. 11, para 1-p. 13, para 3, and p. 15, para 2-p. 16, para 3, teach methods of treating a mixture of polymorphic alleles that are representative of a trait of interest comprising separating and then re-annealing strands of the mixture, and separating and discarding any mismatches, and wherein the polymorphic allele and its flanking sequences are provided with 3'-overlapping ends for protection from digestion by exonucleases.

***Claim Rejections - 35 U.S.C. § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 17, 18, 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al., (applicant's reference C6, IDS filed 11/22/99), as applied to claims 16 and 22-23 above, and further in view of Grist et al., (applicant's reference C2, IDS filed 11/22/99) and Aldhous, (applicant's reference C1, IDS filed 11/22/99).

a. Nelson et al., (C6), at p. 11, para 1-p. 13, para 3, and p. 15, para 2-p. 16, para 3, teach methods of treating a mixture of polymorphic alleles that are representative of a trait of interest comprising separating and then re-annealing strands of the mixture, and separating and discarding any mis-matches. Nelson et al. teach methods, wherein a single polymorphic allele and its

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flanking regions ("a GATC sequence and at least one base that differs between unrelated allelic fragments", p. 12, para 1) are recovered; methods wherein at least one polymorphic allele and its flanking sequence are hybridized with a mixture of polymorphic alleles and their flanking sequences which do not manifest the trait of interest to provide at least one polymorphic allele or fragment thereof which is characteristic of the trait of interest, wherein at least one polymorphic allele and its flanking sequences is provided with 3'-overlapping ends for protection against exonucleases; and wherein the polymorphic allele(s) and their flanking regions are hybridized to an immobilized array of polymorphic alleles and/or their flanking regions for efficiency of analysis.

b. Nelson et al. do not teach methods wherein the mixture of polymorphic alleles are of a chosen VNTR sequence and their flanking regions, wherein a single VNTR allele and its flanking regions are recovered; methods wherein at least one VNTR allele and its flanking sequence are hybridized with a mixture of VNTR alleles and their flanking sequences which do not manifest the trait of interest to provide at least one VNTR allele or fragment thereof which is characteristic of the trait of interest, wherein at least one VNTR allele and its flanking sequences is provided with 3'-overlapping ends; wherein the VNTR allele(s) and their flanking regions are hybridized to an array of immobilized VNTR alleles and/or their flanking regions, and a kit comprising protocols and reagent for performing said methods.

c. Grist et al., BioTechniques 15 (2), 304-309 (1993) (applicant's reference C2, IDS filed 11/22/99), at p. 304, para 2, p. 305, para 2, and p. 306, para 6, teach that VNTR are particularly amenable to analysis by the PCR and have found widespread use in a variety of

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studies employing DNA polymorphism, and a PCR kit comprising procedures for the analysis of VNTR alleles.

d. Aldhous, Science 265, 2008-2010 (1994) (applicant's reference C1, IDS filed 11/22/99), teach mismatch analysis of polymorphic alleles and the polymorphic alleles immobilized to arrays for efficient identification analysis.

e. It would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to have made and used methods of treating a mixture of polymorphic alleles that are representative of a trait of interest comprising separating and then re-annealing strands of the mixture, and separating and discarding any mis-matches, wherein the mixture of polymorphic alleles are of a chosen VNTR sequence and their flanking regions, wherein a single VNTR allele and its flanking regions are recovered; methods wherein at least one VNTR allele and its flanking sequence are hybridized with a mixture of VNTR alleles and their flanking sequences which do not manifest the trait of interest to provide at least one VNTR allele or fragment thereof which is characteristic of the trait of interest, wherein at least one VNTR allele and its flanking sequences is provided with 3'-overlapping ends for protection against exonucleases; wherein the VNTR allele(s) and their flanking regions are hybridized to an array of immobilized VNTR alleles and/or their flanking regions, and a kit comprising protocols and reagents for performing said methods.

f. One of ordinary skill in the art would have been motivated to have used methods comprising polymorphic alleles that were VNTR alleles, because VNTR alleles are particularly

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amenable to analysis by the PCR and have found widespread use in a variety of studies employing DNA polymorphism, as taught by Grist et al., and methods to analyze said VNTR alleles by immobilization to an array for efficiency of analysis, as taught by Nelson et al. and Aldous. One of ordinary skill in the art would have been motivated to make and use a kit comprising protocols and reagents for the analysis of VNTR alleles, as taught by Grist et al., for ease of use in performing said methods.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC), Ph.D.*, whose telephone number is (703) 308-9355.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

22. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

  
Mark L. Shibuya  
Patent Examiner  
Technical Center 1600  
June 5, 2000